

DESIGN AND EVALUATION OF BUOYANT PULSATILE CAPSULES OF NIFEDIPINE FOR CHRONOTHERAPEUTIC DELIVERY

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(Received 08 January 2026) (Accepted 28 April 2026)

ABSTRACT

This study was aimed to design a floating pulsatile device for a poorly water-soluble drug to reduce hypertension patients' circadian symptoms. An inclusion complex of hydroxypropyl beta-cyclodextrin and nifedipine was created using the solvent evaporation method. The quick-release tablets were developed from the solid inclusion complex, croscarmellose sodium, microcrystalline cellulose, and magnesium stearate. The tablets underwent *in vitro* release and *in vivo* pharmacodynamic studies. Floating pulsatile capsules were made with an enteric capsule body, a non-enteric cap, a delayed-release polymer layer, two quick-release nifedipine tablets, and a polymer base layer. Delayed-release layers were prepared with xanthan gum and K4M or E50. Formulations were evaluated for *in vitro* release, buoyancy and weight uniformity. The optimized floating pulsatile capsule delivered the drug immediately and 8 h later to treat early morning symptoms. This study shows that pulsatile tablets treat both hypertensive peaks, maximizing hypertension therapeutic advantages.